

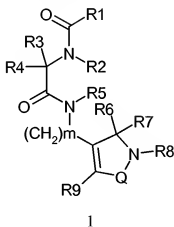
Remarks

Upon entry of the above amendments, this application will contain claims 1-21 and 23-25 pending and under consideration. The application was originally filed with claims 1-23. In a Preliminary Amendment, claims 21 and 22 were canceled and new claims 24 and 25 were added. In the present submission, the claims have been further amended. As discussed more fully below, it is believed that the claims are now patentable. Reconsideration leading to allowance of all pending claims is requested.

I. Provisional Obviousness Double Patenting Rejection

Claims 1-20 and 23-25 were provisionally rejected under the judicially created non-statutory double patenting over the claims 1-34 and 37-74 of the copending application, serial no. 10/510,305 (publication no. US2006/0167268, hereinafter "Evers '268") and claims 1-28, 30-39 and 41-46 of copending application, serial no. 10/380,867 (now allowed, published as US2004/0058971, hereinafter "Dodge"). Reference was made to the species in claim 39 in Evers '268 and the species in claim 46 of Dodge. The applicants respectfully traverse these rejections.

First, in claim 1 of the present application claims a compound of formula 1:



where two alternatives are recited for R3:

1) where each of the C₁-C₆alkylaryl, C₁-C₆alkyl(O)-C₁-C₆alkylaryl, C₃-C₈ cycloalkyl, (C₁-C₆ alkyl) C₃-C₈ cycloalkyl *each which are substituted* and aryl substituted by at least one -SO₂CF₃ group; and R₉ is as recited, or

2) where R₃ is as recited and R₉ is aryl substituted by at least one -SO₂CF₃ group, -O-aryl substituted by at least one -SO₂CF₃ group, -N-aryl

substituted by at least one $-\text{SO}_2\text{CF}_3$ group, or $-\text{S}$ -aryl substituted by at least one $-\text{SO}_2\text{CF}_3$ group.

Consider Dodge first. In the present application, R3, in the first alternative is always a substituted group. R3 can be a *substituted* C1-C6alkylaryl, *substituted* C1-C6alkyl(O)-C1-C6alkylaryl, *substituted* C3-C8 cycloalkyl, *substituted* (C1-C6 alkyl) C3-C8 cycloalkyl; while in Dodge, R3 is an *unsubstituted* C1-C6alkylaryl, *unsubstituted* C1-C6alkyl(O)-C1-C6alkylaryl, *unsubstituted* C3-C8 cycloalkyl, *unsubstituted* (C1-C6 alkyl) C3-C8 cycloalkyl. (See Dodge, claim 1.) Now considering R3 = aryl: for the present application, aryl is substituted with at least one $-\text{SO}_2\text{CF}_3$ group; in Dodge, the aryl can be an optionally substituted aryl. The written specification in Dodge lists suitable substituents at ¶0065¹ but does not include the $-\text{SO}_2\text{CF}_3$ group.

In the present application, R3, in the second alternative, is as recited therein and R9 can be aryl, $-\text{O}$ -aryl, $-\text{N}$ -aryl, or $-\text{S}$ -aryl each *substituted by at least one $-\text{SO}_2\text{CF}_3$ group*; in Dodge, R9 can be aryl, $-\text{O}$ -aryl, $-\text{N}$ -aryl, or $-\text{S}$ -aryl each optionally substituted. Again the written specification lists suitable substituents at ¶0066, but does not include the $-\text{SO}_2\text{CF}_3$ group.

The species recited in claim 46 of Dodge, *i.e.*, 2-(R)-2-(2-Amino-2-methylpropionylamino)-3-phenylmethoxy propionic acid N-(5-(4-chlorophenyl)-3,3-dimethyl-1,1-dioxo-2,3-dihydroisothiazol-4-ylmethyl)-N-ethylamide, the substituent corresponding to R3 is $-\text{CH}_2(\text{O})\text{CH}_2\text{C}_6\text{H}_6$, which is an *unsubstituted* C1-C6alkyl(O)-C1-C6alkylaryl group.

Dodge does not suggest or teach that the groups listed above for R3 can be substituted nor that the $-\text{O}$ -aryl, $-\text{N}$ -aryl, or $-\text{S}$ -aryl groups for R9 be substituted with $-\text{SO}_2\text{CF}_3$. Clearly in light of the above comments, claim 1 of the present application and claim 1 of Dodge are patentably distinct from each other. Claims 2-20 and 23 depend from claim 1. Claims 24 and 25 lists species in which the substituent corresponding to R3 of Figure 1 is a substituted $-\text{CH}_2\text{O}-\text{CH}_2$ -aryl group. These claims are also patentably distinct from those in Dodge.

¹ All citations to Dodge refer to published application US2004/0058971 published 25 March 2004 unless specifically noted to the contrary.

Consider now Evers '268. The applicants will submit an acceptable terminal disclaimer in the present application or that of Evers '268, whichever is found to be allowable last.

II. Rejections under 35 USC § 112.

Claims 3, 4, 23 and 25 are rejected under 35 USC 112, second paragraph.

1) Claim 3 has been amended as suggested in the Office Action by adding the term "or". (Claim 4 depends from claim 3).

Claim 23 has been amended as suggested in the Office Action by reciting to "[a] method for treating ..."

Claim 25 has been amended by deleting the preamble and retaining the recited compound and a pharmaceutically acceptable salt thereof.

Withdrawal of the rejections of claims 3, 4, 23, and 25 is requested.

III. Rejection under 35 USC § 103.

Claims 1-18 and 23-25 are rejected under 35 USC 103(a) over Dodge. The applicants respectfully traverse this rejection and request withdrawal of the rejection pursuant to 35 USC § 103(c).

Dodge is the national stage entry of PCT/US01/27756, filed on 9 Oct. 2001 and published on 25 Apr. 2002 as WO02/32888. The present application is the national stage entry of PCT/US03/08821 filed on 31 Mar. 2003 (published as WO 03/087070) claiming priority to US Provisional patent application nos. 60/371,271; 60/371,270; 60/371,278; 60/371,275; and 60/371,277 all filed on 9 Apr. 2002 --prior the earliest publication date for Dodge. Thus, Dodge is not prior art under §102(a), (b), (c) or (d). Further, the subject matter of Dodge and the present claimed invention were, at the time that the claimed invention was made, subject to an obligation of assignment to Eli Lilly and Co. In support thereof, reference is made to the assignment for Dodge executed in June 2001 and recorded at reel/frame 017928/0291 and the assignment of the present invention also to Eli Lilly and Co. executed in April 2003 and recorded at reel/frame 016807/0958.

In light of the above, withdrawal of the rejections of claims 1-18 and 23-25 is requested.

IV. Amendments

In addition to the comments and amendments above the claims 1-16 and 23-25 have been amended by deleting the term “solvent”, and the word “claim” has been deleted before each claim to confirm to current patent practice.

V. Conclusion

In light of the above comments and amendments reconsideration leading to the withdrawal of all rejections of the claims 1-20 and 23-25 is requested. Applicants respectfully request timely examination of this application leading to allowance of all claims. Additionally the Examiner is invited to contact the undersigned attorney by telephone if there are any questions about this Response or other issues that may be resolved in that fashion.

Respectfully submitted,

/James B. Myers/
James B. Myers
Attorney for Applicants
Registration No. 42,021
Phone: 317-276-0755

Eli Lilly and Company
Patent Division/
P.O. Box 6288
Indianapolis, Indiana 46206-6288

November 17, 2006